

## REMARKS

Claims 1-8 and 11-36 are pending. Claims 1, 6, 15, 16, 23, and 26 are amended in response to the Examiner's comments. The remaining claims are amended to conform to US practice. No new matter is added by these amendments.

### I. Rejections Under 35 USC § 112, second paragraph

Claim 1 was held to be indefinite for recitation of the word "can." In response, claim 1 is amended to replace "can be" with "is." Accordingly, it is believed that this rejection may now be withdrawn.

Claims 16 and 26 were held to be indefinite for recitation of the word "suitable." Accordingly, the word "suitable" is deleted from the claims, and it is believed that this rejection may now be withdrawn.

Claims 23 and 26 were held to be indefinite on the basis that "embedded" appears to be superfluous to "incorporated." In response, the phrase "and/or embedded" is deleted from the claims. Accordingly, this rejection may now be withdrawn.

Claim 15 was rejected as indefinite for recitation of the phrase "vector is further comprises." Claim 15 is corrected by deleted of the word "is." Accordingly, this rejection may now be withdrawn.

### Rejections Under 35 USC § 112, first paragraph

Claim 6 was rejected for lack of enablement. In response, claim 6 is amended as suggested by the Examiner to overcome the rejection. Accordingly, this rejection may now be withdrawn.

### Rejection Under 35 USC § 102(e)

Claims 1-8, 11-15, and 24 were rejected as anticipated by Albert et al. This rejection is respectfully traversed as it may be applied to the amended claims.

Under the standard required for anticipation under § 102, the cited prior art reference is required to disclose every element of the claimed invention. A reference that merely contains substantially the same elements is insufficient to "anticipate" the claimed invention. Jamesbury Corp. v. Litton Industrial Products, Inc., 225 USPQ 253

(Fed. Cir. 1985). Similarly, a reference that only broadly teaches the invention is also considered insufficient to establish anticipation. Kalman v. Kimberly-Clark Corp., 218 USPQ 781 (Fed. Cir. 1983). Further, an anticipatory reference must enable one skilled in the art to make the anticipated subject matter. PPG Industries, Inc. v. Guardian Industries Corp., 37 USPQ2d 1618 (Fed. Cir. 1996).

The invention as claimed. Amended claim 1 is drawn to a therapeutic composition, comprising isolated dermal sheath tissue and/or a cell derived therefrom comprising at least one selected gene, or functional fragment thereof, and wherein said at least one selected gene, or functional fragment thereof is delivered to a target site when said dermal sheath tissue is part of a gene therapy vehicle.

The cited art. Alberts et al. describes a method of producing transgenic hair follicle cells *in vivo* in a transgenic mouse model.

The analysis under § 102(e). Alberts et al. does not disclose or suggest that the therapeutic use of dermal sheath cells genetically manipulated *in vitro* as a cellular gene therapy delivery system to multiple or different cell and tissue sites. Accordingly, it is believed that this rejection is overcome in light of the amendments, and the rejection should be withdrawn.

## Conclusion

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

Respectfully submitted,

  
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1. (Three Times Amended) [An] A therapeutic composition, comprising isolated dermal sheath tissue and/or a cell derived therefrom comprising at least one selected gene, or functional fragment thereof, and wherein said at least one selected gene, or functional fragment thereof [can be] is delivered to a target site when said dermal sheath tissue is part of a gene therapy vehicle.
3. (Three Times Amended) The therapeutic composition of claim 1, [dermal sheath tissue or a cell derived therefrom of Claim 1] wherein said dermal sheath tissue or cell is derived from the lower portion of a hair follicle.
4. (Twice Amended) The therapeutic composition of claim 3, [dermal sheath tissue or a cell derived therefrom of Claim 3] wherein said dermal sheath tissue or cell is derived from a lower third of said hair follicle.
5. (Twice Amended) The therapeutic composition of claim 3, [dermal sheath tissue or a cell derived therefrom of Claim 3] wherein said dermal sheath tissue or said cell is derived from a segment or ring of a combination of follicle/tissue cells.
6. (Three Times Amended) [A] The gene therapy vehicle [according to Claim] of claim 2, which is engineered by recombinant techniques so as to include at least one insertion site into which at least one selected gene [can] is be placed.
7. (Three Times Amended) [A] The gene therapy vehicle [according to Claim 6] of claim 6, wherein said selected gene is inserted into said gene therapy vehicle so that the expression of said selected gene results in the provision of the corresponding protein product.
8. (Twice Amended) [A] The gene therapy vehicle [according to Claim 7] of claim 7, wherein said vehicle is provided with multiple insertion sites to carry multiple genes and

wherein when said genes are expressed said gene therapy vehicle provides for the delivery of multiple proteins.

11. (Three Times Amended) [A] The gene therapy vehicle [according to Claim 2] of claim 2, wherein said selected gene for insertion is inserted in frame with the genome of the gene therapy vehicle so as to provide for correct expression of said selected gene.

12. (Three Times Amended) [A] The gene therapy vehicle [according to Claim 2] of claim 2, further comprising a promoter wherein said selected gene is under the transcriptional control of said promoter.

13. (Three Times Amended) [A] The gene therapy vehicle [according to Claim 12] of claim 12, wherein said promoter is an inducible promoter.

14. (Three Times Amended) [A] The gene therapy vehicle [according to Claim 12] of claim 12, wherein said promoter is a constitutive promoter.

15. (Twice Amended) A vector comprising the gene therapy vehicle of [Claim] claim 2 wherein said vector [is] further comprises

(i) at least one insertion site for at least one selected gene, or functional fragment thereof, and

(ii) other expression control elements for ensuring that once the vector infects or penetrates said tissue and/or cells of said gene therapy vehicle, expression of said selected gene can take place.

16. (Twice Amended) A therapeutic composition comprising a [suitable] carrier and the gene therapy vehicle [according to Claim] of claim 2.

17. (Twice Amended) [A] The therapeutic composition [according to Claim 16] of claim 16, wherein said composition has anti-bacterial properties.

18. (Twice Amended) [A] The therapeutic composition [according to Claim 16] of claim 16, wherein said composition has anti-septic properties.
19. (Three Times Amended) [A] The therapeutic composition [according to Claim 16] of claim 16, wherein said composition further comprises growth promoting additives.
20. (Three Times Amended) [A] The therapeutic composition [according to Claim 16] of claim 16, wherein said composition further comprises at least one anaesthetic.
21. (Three times Amended) [A] The therapeutic composition [according to Claim 16] of claim 16, for topical application wherein said therapeutic composition is provided in a suitable carrier solution, gel, cream, or emollient.
22. (Three Times Amended) [A] The therapeutic composition [according to Claim 16] of claim 16, wherein said therapeutic composition comprises a carrier solution as said carrier.
23. (Three Times Amended) A therapeutic appliance [that comprises a] comprising the therapeutic composition [according to Claim] of claim 16, wherein said carrier is incorporated [and/or embedded] therein, and/or attached thereto, a plaster or bandage.
25. (Three Times Amended) [A] The gene therapy vehicle [according to Claim 24] of claim 24, which acts as a wound healing system.
26. (Three Times Amended) A wound healing system comprising a [suitable] matrix material having incorporated [and/or embedded] therein, and/or attached thereto, [a] the gene therapy vehicle [according to Claim] of claim 24.
28. (Three Times Amended) [A] The wound healing system [according to Claim 26] of claim 26, wherein said matrix material comprises collagenous gels or lattices constructed from reconstituted collagen.

29. (Three Times Amended) [A] The wound healing system [according to Claim 28] of claim 28, wherein said matrix material comprises components from an extra cellular matrix.

31. (Three Times Amended) [A] The wound healing system [according to Claim 30] of claim 30, for treatment of acute, and/or chronic, and/or minor, and/or severe, wound healing.

34. (Three Times Amended) [A] The wound healing system [according to Claim 33] of claim 33, wherein one of said cell types, in addition to said dermal sheath tissue, and/or said cell derived therefrom, comprises dermal papilla tissue.

36. (Three Times Amended) [A] The therapeutic composition [according to Claim 34] of claim 34, wherein one of said cell types, in addition to said dermal sheath tissue, and/or said cell derived therefrom, comprises dermal papilla tissue.